Conquest® 40 PTA Dilatation Catheter

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-303-2664
Fax:	480-449-2546
Contact:	Ashley Fickett, Regulatory Affairs Associate
Date	January 13, 2012

Subject Device Name:

Device Trade Name:	**Conquest® 40 PTA Dilatation Catheter**
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code DQY, LIT)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- Conquest® PTA Balloon Dilatation Catheter (K083657, cleared December 24, 2008)
- Dorado® PTA Balloon Dilatation Catheter (K072283; cleared September 19, 2007)

Device Description:

The Conquest® 40 PTA Dilatation Catheter is a high pressure percutaneous transluminal angioplasty (PTA) balloon catheter consisting of a 0.035" compatible over the wire catheter with a low profile balloon fixed at the distal tip. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes an atraumatic tip to facilitate advancement of the catheter to and through the stenosis. The proximal portion of the catheter includes a female luer lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen.

Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft. A stylet is placed into the tip of the catheter to aid in rewrap/refolding of the balloon. This product is not manufactured with any latex.

Attribute	Conquest® 40 PTA Dilatation Catheter Product Offering
Balloon Diameter (mm)	4, 5, 6, 7, 8, 9, 10, 12
Balloon Length (cm)	2, 3, 4, 6, 8, 10
Catheter Shaft Lengths (cm)	50, 75
Introducer Sheath Compatibility (compatible balloon diameters, mm)	6F: (4, 5, 6, 7, 8) 7F: (9,10) 8F: (12)

Indications for Use of Device:

Conquest® 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Comparison of Indications for Use to Predicate Devices:

The indications for use statement for the subject device, the Conquest® 40 PTA Dilatation Catheter, is a combination of the two predicate devices, the Conquest® PTA Balloon Dilatation Catheter and the Dorado® PTA Balloon Dilatation Catheter. There are no new indications outside of the previously cleared predicate devices. Therefore, the Conquest® 40 PTA Dilatation Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices, the Conquest® PTA Balloon Dilatation Catheter and the Dorado® PTA Balloon Dilatation Catheter. Therefore, the subject device, the Conquest® 40 PTA Balloon Dilatation Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:

The Conquest® 40 PTA Dilatation Catheter has the following similarities to the predicate devices:

- Similar intended use (both predicates)
- Similar indications for use (combination of both predicates)
- Same target population (both predicates)
- Same fundamental scientific technology (both predicates)
- Same operating principle (both predicates)
- Same packaging materials and configuration (Dorado)
- Same sterility assurance level and method of sterilization (both predicates)

Performance Data:

To demonstrate substantial equivalence of the subject device, the Conquest® 40 PTA Dilatation Catheter to the predicate devices, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed:

- Tip Length
- Balloon Outer Diameter
- Shaft Outer Diameter
- Balloon Distensibility

- Fatigue
- Fatigue in a Stent/Stent Graft/Graft
- Balloon Burst Strength in a Stent/Stent Graft and Balloon Removal
- Balloon Inflation and Deflation Time
- Balloon Burst Strength and Burst Mode
- Balloon to Shaft Tensile Force
- Catheter Shaft Elongation
- Guidewire Extension to Bifurcate Tensile Force
- Bifurcate to Shaft Tensile Force
- Guidewire Hub to Guidewire Extension Tensile Force
- Introducer Sheath Compatibility
- Catheter Shaft Leaks
- Trackability and Guidewire Compatibility
- Syringe Inflation Pressure Capability

The following *in vitro* tests were leveraged from the predicate devices, the Conquest® PTA Balloon Dilatation Catheter and the Dorado® PTA Balloon Dilatation Catheter:

- Balloon Operating Pressure
- Balloon Length
- Marker Band Visibility
- Marker Band Alignment
- Tip Taper
- Tip Visibility
- Tip Tensile
- Shaft Visibility
- Shaft Length
- Balloon Hub to Balloon Extension Tensile Force
- Balloon Extension to Bifurcate Tensile Force
- Media Interaction
- Guidewire Lumen ID
- Equipment Interface
- Packaging Tensile Strength

The results from these tests demonstrate that the technological characteristics and performance criteria of the Conquest® 40 PTA Dilatation Catheter are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the similar intended use.

Biocompatibility:

To demonstrate substantial equivalence of the subject device, the Conquest® 40 PTA Dilatation Catheter, to the predicate devices, the following biocompatibility testing was performed in accordance ISO 10993-1:2010, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process," and "Blue Book Memorandum – G95-1 Use of International Standard ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."

- Cytotoxicity
- Chemical Characterization

Since all materials in the subject device, the Conquest® 40 PTA Dilatation Catheter, are utilized in the predicate devices, the Conquest® PTA Balloon Dilatation Catheter and the Dorado® PTA Balloon Dilatation Catheter, the following biocompatibility tests were leveraged from the predicate devices:

- Irritation/Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility (Hemolysis and Thrombogenicity)

The results from these tests demonstrate that the subject device, the Conquest® 40 PTA Dilatation Catheter, is comparable to the predicate devices and that it is considered safe and biocompatible for its intended use.

Conclusions:

The subject device, the Conquest® 40 PTA Dilatation Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Conquest®

40 PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Conquest® PTA Balloon Dilatation Catheter and the Dorado® PTA Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

Bard Peripheral Vascular, Inc.
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K120660
Trade/Device Name: Conquest 40 PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (Two)
Product Code: LIT, DQY
Dated: March 2, 2012
Received: March 5, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Conquest® 40 PTA Dilatation Catheter

Indications for Use: The Conquest® 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120660